

REMARKS/ARGUMENTS

Applicants submit the aforementioned amendments in response to the Office Action mailed March 7, 2007.

Claims 1-10 are pending, among which claims 1, 3-4 and 6-10 are cancelled and only claims 2 and 5 are subject to the examination.

Claims 2 and 5 have been amended.

Reconsideration is respectfully requested in view of the above amendment and the following remarks.

Rejection under 35 USC 112, first paragraph

The Examiner rejects claims 2 and 5 under 35 USC 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner considers the term “a mutated RT inhibitor” as new matter. Applicants have deleted such claim language. Accordingly, the rejection under 35 USC 112, first paragraph has been overcome and should be withdrawn.

Rejection under 35 USC 103(a)

The Examiner rejects claims 2 and 5 under 35 103(a) as being obvious over Stein et al. in view of Servais et al.

Stein et al. isolated a large number of HIV reverse transcriptase mutants from AZT treated patients, but none of the HIV reverse transcriptase mutants isolated by Stein et al. contains a mutation 194G, i.e., a glycine at position 194 changed from the wild type amino acid. Stein et al. also does not teach how to evaluate the effectiveness of a reverse transcriptase inhibitor or a change in the drug susceptibility.

Servais et al. merely identifies a drug resistant mutation 194G and nothing else.

The present invention is directed to a method of evaluating the effectiveness of a drug based on the RT mutation 194G. The method requires, among others, that the mutation 194G must be identified and the response of such mutation to an RT inhibitor must be compared with the response of an HIV strain that does not contain such mutation. There is no such teaching or suggestion in neither cited references. Merely identifying a drug resistant mutation 194G, as

Servais et al. did, does not give a rise to an analysis that methodologically and specifically look for such a mutation in a sample as the basis for a drug therapy, let alone to a comparison with a sample that does not contain such mutation.

For the two cited references to be combined, there must be some motivation or reason to do so. The Examiner has found such motivation in the claim language but improperly determined that “a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and prior art in order to patentably distinguish the claimed invention from the prior art.” It is true that when a claim is anticipated by a prior art reference, the recitation of intended use cannot save the claim under the anticipation by inherency doctrine, because the inherent property would necessarily flow from the claimed manipulative steps or the structure, which would be fully disclosed in the anticipating reference. See *Bristol-Myers Squibb Co. v. Ben Venue Lab. Inc.* 246 F.3d 1368 (Fed. Cir. 2001). However, applicants are not aware any legal authorities that the anticipation by inherency doctrine has been applied to determine obviousness. Logically, it cannot, because obviousness requires a motivation or reason to read the references on the objected claim. Absent such motivation, an invention cannot be rendered obvious. Thus, the “intended use” as stated by the Examiner is highly relevant with respect to determination of obviousness.

It should be noted that a motivation to combine the references must be provided from the outside of the instant application. Here, there is none. But the Examiner found the motivation in the instant application and applied it to the cited references to conclude that the claimed invention is obvious. Applicants respectfully submit that such combination of the references is inappropriate, and at the very least, is a hindsight approach that is prohibited by law.

Further more, the HIV reverse transcriptase has more than two hundred amino acids. In other words, there could be at lease over two hundred mutations, without considering that each amino acid could be mutated to 20 different others. Selection of one single amino acid mutation, i.e., 194G, as the basis for the evaluation of effectiveness of an RT inhibitor would be undue experimentation, given the large number of variations, unless the cited references provide a specific reason to do so. Again, there is none.

For the forgoing reasons, applicants respectfully submit that claims 2 and 5 cannot be rendered obvious by Stein et al. and/or Servais et al.

Allowance of claims 2 and 5 is respectfully requested.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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